

REMARKS

Claim 4 has been cancelled herein, and claims 6, 7 and 8 have been amended to correct dependencies. No new matter has been added by virtue of the amendments. Claims 1, 2, and 6-11 remain pending and under consideration.

Rejection under 35 USC § 101

Claims 1, 2, 4, and 6-11 were rejected under 35 USC §101 as purportedly lacking support of either a specific or substantial asserted utility or a well established utility. The Examiner has maintained the rejection under 35 USC §101 seemingly because he believes no specific disorder has been disclosed or asserted, and no other specific or substantial utility is asserted or supported in the specification as filed. Applicants reiterate traversal of the rejection.

Applicants submit the disclosure of a new human acyltransferase, such as 56919, would be well understood to those of skill in the art to have an immediately recognizable, well established utility as a composition useful for identification of novel diagnostics and therapeutics for assessment and modulation of human triglyceride and lipid biosynthesis and metabolism of bioactive lipids. Furthermore, the utility of novel diagnostics and therapeutics for assessment and modulation of triglyceride and lipid biosynthesis and metabolism of bioactive lipids is well known to have utility in disorders of metabolism and cardiovascular indications. For example, statins, which inhibit cholesterol biosynthesis are a treatment of choice for many patients with increased risk factors for coronary heart disease(e.g., high LDL). However, such treatments are not applicable to patients with all risk factors for CHD, such as low HDL or hypertriglyceridemia. Thus, it would be readily recognized that alternative approaches to modify triglyceride and lipid biosynthesis and metabolism of bioactive lipids would be useful. As such, Applicants submit a well established utility is supported in the subject application.

Furthermore, the specification asserts use of the described compositions in methods for diagnostics and identification of therapeutics for disorders, including, for example, metabolic disorders. As acknowledged by the Examiner, the instant application has provided a description of an isolated nucleic acid sequences of SEQ ID NO:1 and SEQ ID NO:3, encoding an acyltransferase protein and the amino acid sequence of SEQ ID NO:2. The Examiner, however, holds the position that no specific disorder, whether a metabolic disorder or otherwise specific disorder has been identified. Applicants respectfully disagree. For example, Applicants have in fact stated hypertriglyceridemia as one metabolic disorder in which the claimed compositions as well as methods of using the compositions would be useful for development of diagnostics and/or therapeutics (see, e.g., at page 10, line 37, page 50, line 21, and claims 29, 35, and 38 in the application as filed). Such assertion is further supported in the exemplification at Example 5, page 86, where 56919 is upregulated in a marmoset cholestyramine model where elevated serum triglyceride levels are demonstrated.

Applicants respectfully submit the utility rejection set forth in the present instance is therefore improper as a rebuttal of the asserted utility has not been effectively made in the present case. The steps that should be taken in order to make an effective rejection should fall under MPEP 2107 (II)(C), where the Examiner is required to make a proper *prima facie* showing of no specific and substantial credible utility. See MPEP 2107(II)(C) (emphasis added):

*(1) Where the asserted utility is not specific or substantial, a prima facie showing **must establish that it is more likely than not** that a person of ordinary skill in the art would not consider that any utility asserted by the applicant would be specific and substantial.*

*The prima facie showing **must contain the following elements:***

(i) An explanation that clearly sets forth the reasoning used in concluding that the asserted utility for the claimed invention is not both specific and substantial nor well-established;

*(ii) **Support for factual findings** relied upon in reaching this conclusion; and*

*(iii) An evaluation of **all relevant evidence of record**, including utilities taught in the closest prior art.*

The Examiner has not made a sufficient showing to establish more likely than not the utility set forth in the present specification would not be specific, substantial or well established, as sufficient support or factual findings have not been relied upon to make such a showing to rebut Applicants' assertion that the use of the claimed compositions in diagnostics assays and/or identification of therapeutics would more likely than not be useful. Rather, the Examiner relies on general arguments to back up the claim that Applicant's original assertion is neither specific nor substantial. Applicants respectfully submit the Examiner's imposition of the present rejection is improper in view of the utility guidelines and MPEP §2701.

Thus, Applicants' specification as filed supports a well established utility, which would have been credible to one skilled in the art at the time of invention. Furthermore, an asserted, specific substantial credible utility is clearly disclosed in the instant specification as filed. As such, it is believed Applicants have met the requisite burden in order to establish the requirements for utility. The Examiner, however, has not made a *prima facie* showing to effectively rebut either the well established, or asserted utility. Applicants therefore respectfully request the Examiner's rejection under 35 U.S.C. §101 be reconsidered and withdrawn.

Rejections under 35 USC § 112

Claims 1, 2, 4, and 6-11 were rejected under 35 USC 112, first paragraph, since the application lacks a specific or substantial asserted utility or a well established utility. Applicants respectfully traverse

the rejection. For the reasons discussed *supra*, the presently pending claims do in fact have a specific substantial asserted utility which would be well recognized to one of skill in the art at the time of filing of the applications. Reconsideration and withdrawal of the rejection is requested.

Claims 4, and 6-11 were rejected under 35 USC 112, first paragraph as not enabling. The rejection is traversed.

Applicants again reiterate traversal of the rejection. Applicants submit the application as filed provides each of the necessary elements to carry out the subject matter of now pending claims 4, and 6-11. For the reasons discussed in Applicants' prior response, the tools required to carry out generation and/or identification of peptides, testing of bioactivities and identification of polypeptides comprising at least 50 consecutive amino acids having an acyltransferase activity are readily available to those of skill in the art in view of Applicants' disclosure and the knowledge of those skilled in the art, and the specification as filed does in fact support an enabling disclosure of claims 4, and 6-11.

However, solely in an effort to advance prosecution, Applicants have amended the claims to cancel claim 4 and amend claims 6, 7, and 8 to correct dependencies. It is believed the present amendment renders the rejection moot. Reconsideration and withdrawal of the rejection is thus respectfully requested.

In view of these amendments and remarks, Applicants respectfully submit that the objections and the rejections of the claims under 35 USC §§ 101 and 112 are now overcome and that this application is now in condition for allowance. Early notice to this effect is solicited. If a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned.

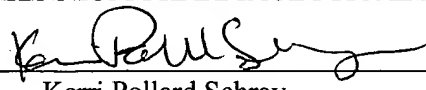
This paper is being filed timely as a request for a two month extension of time is filed concurrently herewith. It is believed no additional fees or extensions of time are required. In the event any additional fees or extensions of time are necessary, the undersigned hereby authorizes the requisite fees to be charged to Deposit Account No. 501668.

Entry of the remarks made herein is respectfully requested.

15 February 2005

Respectfully submitted,

MILLENNIUM PHARMACEUTICALS, INC.

By 
Kerri Pollard Schray
Registration No. 47,066
40 Landsdowne Street
Cambridge, MA 02139
Telephone - 617-551-3676
Facsimile - 617-551-8820